K022641

OCT 02 2002

Exhibit D

510(k) Summary

Submitted by: Daniel J. Manelli
Manelli Denison & Selter, P.L.L.C.
2000 M Street, NW (Suite 700)
Washington, DC 20036

Telephone: 202-261-1000

On behalf of Tokuyama America, Inc.
510(k) Submission: Tokuyama Rebase II
August 7, 2002

The product is a chairside denture relining material for relining, repairing and rebasing removable dentures. It is substantially equivalent to the company's Tokuso Rebase (K896981). The product is offered in two versions of differing in curing time; *i.e.*, Fast and Normal. The product complies with ADAS No. 17 and has been approved for marketing by the Japanese Ministry of Health and Welfare.

The product is for use only by dental practitioners; it is not intended for OTC use. It contains materials that pose no health hazard when used according to directions.

The use of the product is contra-indicated for patients who are allergic to methacrylate monomers or organic solvents. It should not be allowed to come into contact with skin, eyes or clothing. Should contact with the eyes occur, the eyes should be thoroughly flushed with water followed by immediate contact with a physician.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 2 2002

Tokuyama America, Inc.
C/O Mr. Daniel J. Manelli, Esq.
Manelli, Denison, & Selter, PLLC
2000 M Street, N.W., 7th Floor
Washington, DC 20036-3307

Re: K022641
Trade/Device Name: Tokuyama Rebase II
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: August 07, 2002
Received: August 08, 2002

Dear Mr. Manelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit C

510(k) Number (if known): K012641

Device Name: Tokuyama Rebase II

Indications For Use:

For relining denture surfaces, to repair a fractured denture, or to form a new denture base.

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K012641

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)